FDA NEWS

THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FDA INFORMS PUBLIC OF NATIONWIDE INFANT FORMULA RECALL

The U.S. Food and Drug Administration (FDA) is alerting the public to a recall being conducted by Mead Johnson for their GENTLEASE powdered infant formula, lot number: BMJ19, use by 1 Jul 07. This lot was found to contain metal particles, consisting of up to 2.7 millimeter in size.

No illnesses have been reported to date. However, in the rare instance that an infant was to inhale the infant formula into the lungs, the presence of these particles could present a serious risk to the infant's respiratory system and throat. Any injuries associated with this problem would be likely to show up within three to four hours. The symptoms could be varied depending on whether there is damage to the throat or lungs. Damage to the throat may include coughing, difficulty swallowing or difficulty breathing. Similarly damage to the lungs could include coughing and difficulty breathing. If you may have fed this lot of GENTLEASE to your baby, and you have any concerns about your baby's health, you should contact your baby's health professional for guidance.

There were approximately 41,464 24-ounce cans of this lot of recalled product distributed, beginning on December 16, 2005, through many major retail stores across the country, so the consumer should concentrate on the code on the can rather than on the place of purchase. The affected products can be identified by the lot number and expiration/use by date embossed on the bottom of the can of BMJ19, use by 1 Jul 07.

Mead Johnson informed the FDA of this problem. FDA and Mead Johnson are currently investigating the cause of the metal particles found in the infant formula in this highly unusual incident.

Consumers who have a can of this batch of GENTLEASE powdered infant formula should not use the product and should contact Mead Johnson at 888-587-7275 immediately.

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